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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,610	01/11/2001	Jonathan S. Stamler	Duke File No. 1838	8014

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10/21/2002

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 10/21/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/757,610

Applicant(s)

STAMLER ET AL.

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☒ Claim(s) 9 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-20 are pending.

Applicant's election with traverse of Group I , claims 1-7 and 15-20 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that all claims should have the same area of search and the groups do not have independent classification. This is not found persuasive because Group I is classified in class 424, subclass 43 and Group II is classified in class 514, subclass 18. Both groups have different classes and subclasses, necessitating different searches. The groups do have independent classification according to the different class and subclass of each group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-7 and 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group I, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 8-14 are examined on the merits.

The Information Disclosure Statements filed March 29, 2001 and July 16, 2002 have been considered. A signed copy of the PTO-1449 form is attached hereto.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering an inhibitor of glutathione-dependent formaldehyde dehydrogenase does not reasonably provide enablement for killing or reducing the growth of pathologically proliferating mammalian cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification fails to provide information that would allow the skilled artisan to practice the invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CFAC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (Bld Apls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction and guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,

- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art,
- 8) the breadth of the claims.

The quantity of experimentation necessary would be undue. The working examples lack sufficient data. Therapies involving cancer and pathologically proliferating cells are unpredictable (see Gura, Science, November 7, 1997, vol. 278, pp1041-1042). In Gura, column 1, 2<sup>nd</sup> paragraph “ The fundamental problem in drug discovery for cancer is that the model systems are not predictive at all.” Column 1, 3<sup>rd</sup> paragraph further states “ The animals apparently do not handle the drugs exactly the way the human body does.”

The amount of direction and guidance provided is lacking. The working examples lack sufficient data to understand if the clinical results will invariably occur. The specification does not teach how to assess and/or modify each of the variables necessary for the therapy to work.

The working examples provided lack sufficient data to determine how to avoid the pitfalls in the process of using the therapy.

The nature of the invention is concerned with providing therapy for pathologically proliferating mammalian cells. The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to provide effective therapy for pathologically proliferating mammalian cells.

The state of the prior art is unpredictable when involved with therapies for cancer and pathologically proliferating mammalian cells. ( Gura, Science, vol. 278, 1997, pp. 1041-1042).

The relative skill of those in the art would be a practicing MD skilled in clinical research.

The predictability of the art is that cancer therapies and therapies for pathologically proliferating mammalian cells are unpredictable.

The breadth of the claims- the rejected claims are directed to therapies for cancer and pathologically proliferating mammalian cells but the specification does not so demonstrate.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8, line 1 "...pathologically proliferating cells..." is vague and indefinite. What types of pathologically proliferating cells? The specification does not give a standard for determining how much proliferation is pathological.

Claim 9, line 1 "...pathologically proliferating cells..." is vague and indefinite. What types of pathologically proliferating cells?

Claim 9, line 2 "...pathologic bacteria or fungus..." is vague and indefinite. What types of pathologic bacteria or fungus? The specification does not teach the metes and bounds of a pathologic bacteria or fungus. How is pathologic determined or taught in the specification?

Claim 9, line 2 "...bacterial or fungal infection..." is vague and indefinite. Any bacterial or fungal infection is included?

Claim 9, line 2 "... afflicted with a bacterial or fungal infection..." is vague and indefinite. It is unclear if the recited infections are limited to a pathological infection or if some other undefined bacterial or fungal infection is encompassed.

Claim 9, line 3 "...reduces the growth..." is vague and indefinite. To what degree is the growth reduced? How is growth reduction measured? What is the standard for measurement?

Claim 9, line 3 "...pathologic bacteria or fungus..." is vague and indefinite. What types of pathologic bacteria or fungus?

Claim 10, line 1 "...pathologically proliferating cells..." is vague and indefinite. What types of pathologically proliferating cells?

Claim 10, line 2 "...reduces the growth..." is vague and indefinite. To what degree is the growth reduced?

Claim 10, line 3 "... pathologically proliferating mammalian cells." is vague and indefinite. What types of pathologically proliferating mammalian cells?

Claim 11, line 1 "...pathologically proliferating mammalian cells." is vague and indefinite. What types of pathologically proliferating mammalian cells?

Claim 12, line 1 "...pathologically proliferating mammalian cells." is vague and indefinite. What types of pathologically proliferating mammalian cells?

Claim 12, line 2 "... in small cell being carcinoma..." is indefinite. The specification discloses small cell lung cancer on page 20, line 17; however it does not disclose "small cell being carcinoma". Thus, the metes and bounds of the claimed invention cannot be determined.

Claim 13, line 1 "...pathologically proliferating cells..." is vague and indefinite. What types of pathologically proliferating cells?

Claim 14 depends upon a rejected claim, claim 8.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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1654  
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